K070963

MAY - 4 2007

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Summary of Safety and Effectiveness
ReUnion™ HA Fracture Stem

Proprietary Name:	ReUnion™ HA Fracture Stem
Common Name:	Shoulder Prosthesis
Classification Name and Reference:	Shoulder joint metal/polymer semi constrained cemented prosthesis. 21 CFR §888.3660 Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis. 21 CFR §888.3690
Device Product Code:	87 KWS, 87 HSD
For Information Contact:	Francisco Haro, Regulatory Affairs Specialist Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430 Phone: (201) 831-5493 Fax: (201) 831-6038
Date Summary Prepared:	April 3, 2007

Description:

This submission is a line extension to the Solar® ReUnion™ Fracture Stem for fracture humeral stem with no CP Ti plasma spray. Fracture humeral stems will be based on the Solar® ReUnion™ Fracture Stem.

Intended Use:

The subject humeral stem is a single-use, sterile device intended for use in shoulder replacement. It is intended for the reconstruction of the proximal humerus. This humeral stem is intended for primary or revision reconstruction of the shoulder joint.

Indications for Use:

For use as a Bipolar Shoulder Replacement:

- Aseptic necrosis of the humeral head

- Painful, disabling joint disease of the shoulder resulting from: degenerative arthritis, rheumatoid arthritis, or post-traumatic arthritis.
- Proximal humeral fractures and/or dislocation.
- Clinical management problems where arthodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
- Pathological conditions or age considerations which indicate a more conservative glenoid procedure and avoidance of the use of bone cement in the glenoid.

For use as a Total Shoulder Replacement:

- Aseptic necrosis of the humeral head
- Painful, disabling joint disease of the shoulder resulting from: degenerative arthritis, rheumatoid arthritis, or post-traumatic arthritis.
- Proximal humeral fractures and/or dislocation.
- Clinical management problems where arthodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.
- Revision of previous unsuccessful total shoulder replacement, resurfacing or other procedure.

Substantial Equivalence:

The ReUnion™ HA Fracture Stem is substantially equivalent to the Solar® ReUnion™ Fracture Stem in regards to intended use, design, materials, and operational principles as humeral components. The engineering analysis demonstrates that the subject components are substantially equivalent in strength to the predicate components.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 4 2007

Howmedica Osteonics Corporation
% Mr. Francisco Haro
Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K070963
Trade/Device Name: ReUnion™ HA Fracture Stem
Regulation Number: 21 CFR 888.3690
Regulation Name: Shoulder Joint humeral (hemi-shoulder) metallic uncemented prosthesis
Regulatory Class: II
Product Code: HSD
Dated: April 3, 2007
Received: April 5, 2007

Dear Mr. Haro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Barbara Bucholz
for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K070963

510(k) Number (if known):

Device Name: ReUnion™ HA Fracture Stem

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- Revision of previous unsuccessful total shoulder replacement, resurfacing or other procedure.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K070963